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Minutes

Agricultural Biotechnology Research Advisory Committee

Working Group on Aquatic Biotechnology and Environmental Safety

October 15, 1992

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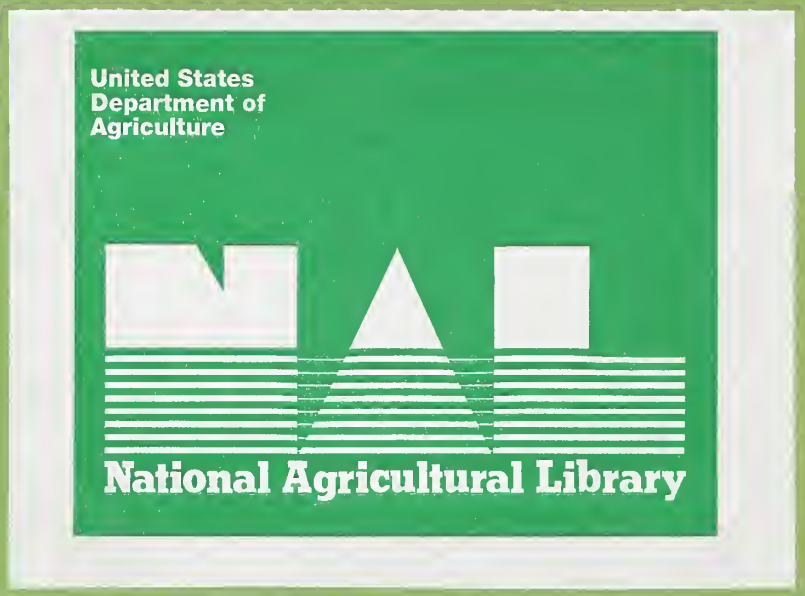
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U.S. DEPARTMENT OF AGRICULTURE
Agricultural Biotechnology Research Advisory Committee

Working Group on Aquatic Biotechnology
and Environmental Safety

Minutes of Meeting
October 15, 1992

Time, Place and Participants

The first meeting of the Working Group on Aquatic Biotechnology and Environmental Safety took place on October 15, 1992, in Room 170 of the Hubert H. Humphrey Institute of Public Affairs at the University of Minnesota in Minneapolis, Minnesota. The meeting had been announced in the Federal Register and was open to the public.

ABRAC Working Group Members and Special Experts present included:

Anne Kapuscinski, Chair, University of Minnesota, St. Paul, MN;

Edward Bruggemann, National Audubon Society, Washington DC;

John Colt, James M. Montgomery Consulting Engineers, Inc., Bellevue, WA;

Rex Dunham, Auburn University, Auburn, AL;

Eric Hallerman, Virginia Polytechnic Institute and State University, Blacksburg, VA;

Harold Kincaid, U.S. Fish and Wildlife Service, National Fisheries R&D Laboratory, Wellsboro, PA;

Roger Mann, College of William and Mary, Virginia Institute of Marine Sciences, Glouchester Point, VA;

Peter Moyle, University of California, Davis, CA;

William M. Witt, Food and Drug Administration, National Center for Toxicological Research, Jefferson, AR;

Maryln Cordle, U.S. Dept. of Agriculture, Office of Agricultural Biotechnology, Washington, DC.

Others in attendance were:

William R. Wolters, U.S. Dept. of Agriculture, Agricultural Research Station, Stoneville MS;

Althaea Langston, U.S. Dept. of Agriculture, APHIS, Hyattsville MD;

Alice Tibbets, Minnesota Sea Grant, St Paul, MN;

John Hynes, Environmental Quality Board, St. Paul, MN.

Call to Order and Preliminaries

Dr. Kapuscinski called the meeting to order at 9:05 a.m. She welcomed the Agricultural Biotechnology Research Advisory Committee (ABRAC) members, special experts, support staff and guests, and asked everyone to introduce themselves.

Dr. Kapuscinski specified two objectives for this meeting:

1) to begin drafting performance standards for aquaculture research systems with modified organisms;

2) to discuss the design of the experts workshop scheduled for next summer.

She suggested a small change to the agenda; that the group break for lunch at 11:30 a.m., rather than 12:00 p.m., to allow for a short trip to look at a potential meeting place for the summer workshop. With this change the agenda was approved.

Dr. Kapuscinski then asked Maryln Cordle, Office of Agricultural Biotechnology, U.S. Department of Agriculture (USDA), to make a short presentation on ABRAC's history with Aquaculture Biotechnology.

ABRAC's History with Biotechnology

Ms. Cordle thanked the Working Group and experts for agreeing to participate in this important activity and expressed her confidence that the Working Group's efforts will result in a major scientific contribution regarding performance standards for conducting biotechnology research with fish, crustaceans and mollusks.

USDA's Interest

She then gave a short background on USDA's interest in this activity, explaining that USDA is currently committing about $20.3 million annually to aquaculture research. She said this figure may increase in the future in response to growing consumer demand for affordable, high quality seafood and the need to protect oceans and fresh water resources from over harvesting. She explained that USDA has an interest in promoting promising research using the full spectrum of biotechnology now available, while also wanting to ensure that the risks of conducting that

research are appropriately considered and managed. She explained that the National Environmental Policy Act (NEPA) directs all Federal agencies to give appropriate consideration to environmental consequences of proposed actions in their decision making (including decisions to fund research activities), and requires preparation of detailed environmental statements on major Federal actions significantly affecting the quality of the human environment.

Past Experience

Ms. Cordle recounted the USDA's experience with evaluating aquaculture research with transgenic organisms. She referred specifically to the proposal by the Alabama Agricultural Research Station at Auburn University to extend Dr. Rex Dunham's indoor research program on transgenic fish to studies in outdoor ponds. Ms. Cordle explained that in the course of considering the potential environmental effects for the two transgenic fish studies proposed by Auburn University, the USDA spent $250,000. Based on this experience, she said that USDA decided there was a need to develop scientifically-based performance standards that one could readily apply to determine that a particular research study could be conducted safely.

Funding for the Activity

Ms. Cordle gave a summary of how the Working Group began, and explained its charge. She explained that at the March 1992 meeting of ABRAC, Dr. Kapuscinski was asked to chair a Working Group on Aquatic Biotechnology and Environmental Safety and to consider the feasibility of undertaking the development of performance standards for research in contained ponds. She noted that the Office of Agricultural Biotechnology obtained $10,000 from the Study Evaluation Funds of the Assistant Secretary for Science and Education to undertake planning the experts workshop. She also noted that Dr. Kapuscinski expects to receive funds from the State of Minnesota to convene an experts workshop.

Scope of the Activity

Ms. Cordle explained that the scope of the activity of the Working Group is to develop performance standards for biotechnology research on fresh water and marine fish, crustaceans and mollusks. She emphasized that while the standards may have some relevance for commercial activities as well, commercialization includes additional considerations that USDA considers to be beyond the scope of the performance standards to be developed by the Working Group.

Ms. Cordle explained that the development of performance standards for research is strictly a science-based activity intended to be useful to the research community. She stressed

that appointed groups within the Federal government are currently addressing regulatory issues, and that the mechanisms by which the research standards developed by the Working Group might be implemented by institutions or regulatory agencies is outside the task of the Working Group.

Risk-Based Approach

Ms. Cordle explained that the standards developed should be based on risk, which is a function of the characteristics of the organism and the environment into which it is introduced, and is independent of the method by which the organism is produced. She noted that the environmental introduction of modified aquatic species is of particular concern because most species developed for seafood production are not far removed from their wildtype and are more likely to survive unaided in the environment than terrestrial crop plants or livestock developed for food, which depend on human management for survival. She noted, too, that once these aquatic organisms become established, eradication or control may be difficult and expensive to achieve.

Ms. Cordle suggested that, in developing the performance standards, the Working Group could build on the scientific concepts in a number of previous reports.

1) National Institutes of Health, "Recombinant DNA; Notice of Advisory Committee Meeting and Proposed Actions Under Guidelines for Research, Federal Register of August 11, 1987, 52 FR 29800. Proposed Appendix Q to the NIH Guidelines for Research Involving Recombinant DNA Molecules addresses animal research, including aquatic species, conducted in a laboratory or hatchery facility.

2) "The Guidelines for Research Involving Planned Introduction into the Environment of Genetically Modified Organisms," published as a supplement to minutes of the Agricultural Biotechnology Research Advisory Committee meeting, December 3-4, 1991.

3) Tiedje, et al. "The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations, Ecology, Vol. 70, No. 2, April 1989.

4) National Research Council, "Field Testing Genetically Modified Organisms: Framework for Decisions," National Academy Press, 1989. The concept of "familiarity" may be of particular interest.

5) Research Protocol, Appendix H of "Proposed Aquatic Nuisance Species Program," as announced in the Federal Register of November 19, 1992.

Ms. Cordle agreed to provide copies of these documents to those who do not already have them.

What are Performance Standards?

Ms. Cordle explained that a performance standard should set ends or goals, rather than specifying a particular means to achieve them (a characteristic of a design standard). A performance standard, in contrast to a design standard, allows the researcher flexibility in choosing the best means to comply with the standard. She emphasized that the standards should avoid being prescriptive. However, where appropriate, "how to" examples may be useful for illustration purposes.

In response to a question by Dr. Dunham, Ms. Cordle said the standards are intended as voluntary guidance. While they could conceivably be adopted as regulations at some later stage, implementation policy is not the concern of the Working Group. The Working Group's task is to develop good science-based voluntary standards for research.

Need for Performance Standards

Dr. Kapuscinski made a short presentation on the need for performance standards.

She explained that biotechnologic tools make it possible to create novel hereditary traits or to modify the regulation of traits in order to produce phenotypes desired in aquaculture. She listed some examples of new or modified traits: increased growth rates, improved feed conversion efficiencies, freeze resistance, and resistance to specific disease agents, and noted there are other traits of interest to aquaculture researchers.

She said that the performance of aquacultural organisms expressing one or more of these novel or modified traits may prove to be ecologically novel, which has raised questions in the scientific community about the ecological risks associated with such modified aquacultural organisms. Dr. Kapuscinski explained that standards are important because of the potential for ecological impacts of accidental escapes or planned introductions into natural aquatic ecosystems, particularly in light of the fact that accidental escapes of non-modified organisms from aquaculture systems have been documented frequently.

Dr. Kapuscinski explained that in order to assess their commercial viability, aquacultural organisms with modified traits must be evaluated as part of different aquaculture systems, and that performance evaluations in contained and confined systems are needed to better assess their ecological role.

She also commented that current scientific uncertainty about commercial viability and ecological role is a deterrent to investment in research and development involving these organisms.

Dr. Kapuscinski then noted that aquaculture systems are diverse, both in terms of organisms and physical components. She defined an aquaculture system as including the type of organism, the culture methods and the physical facility and pointed out that no standard currently exists for determining whether a particular aquaculture system constitutes containment, confinement, or environmental introduction.

She concluded by stating that if the Working Group can develop generic performance standards this will encourage research on and development of aquacultural organisms with novel hereditary traits while reducing the risks of detrimental impact on natural aquatic ecosystems.

Discussion on Ms. Cordle's and Dr. Kapuscinski's comments:

Dr. Moyle raised the point that in some cases aquacultural organisms are not too different from other domesticated animals, and in fact the more domesticated they are, the less ecological impact can be expected. Dr. Kapuscinski agreed and expressed interest in the group's input on assessing what is an adequate degree of domesticity, to dismiss concerns about escape or introduction of the organism.

Dr. Kincaid pointed out that even a low probability for adverse ecological impact may not be adequate if releases are large and the organisms exist for several generations in the ecosystem.

Dr. Moyle responded that there will be no way to eliminate risk, and said he hopes that alterations that improve performance in captivity will be found to decrease performance in the wild, as he suspects they might.

Dr. Mann pointed out that the relevance of domesticity may not apply to marine species. Only a handful of marine species are cultivated. They are present worldwide and their chances of survival in the wild even with further domestication are high, as their history of culture, which is "one of abuse," illustrates their tolerance to environmental variability. Marine species are particularly robust and able to survive without human care.

Dr. Moyle noted that some species are becoming less hardy through genetic alteration. In addition, some research simultaneously develops the handling and harvest technology and the genetic traits (for example, tomatoes). It might be possible to design organisms that will not survive when separated from the aquaculture system.

Ms. Cordle pointed out that the ability of an organism to survive and become established is not necessarily a concern; only if it poses a threat is it a concern.

Dr. Mann pointed out how difficult it is to make generalities about expected impacts of organisms because the same organism can have very different impacts, depending on the ecosystem into which it is introduced.

Dr. Dunham noted that some of these questions will be addressed in the draft standards.

Form and Content of Proposed Performance Standards

Dr. Kapuscinski presented a short flow chart summarizing the draft performance standards she and Dr. Hallerman drafted (Appendix A). She also passed out a discussion draft that provided more detail on the five proposed components of the standards: 1) characteristics of the modified organism, 2) characteristics of the receiving ecosystem, 3) culture methods, 4) physical confinement, and 5) inspection (Appendix B). A list of specific questions and areas requiring further input was also provided to stimulate discussion (Appendix C).

Characteristics of the Modified Organism:

Dr. Kapuscinski suggested including a question in the introduction to the standards that asks the researcher to consult the Research Protocol developed by the Aquatic Nuisance Species Task Force, when relevant, and to then return to this document.

In response to Dr. Kapuscinski's question, Dr. Langston explained that the Aquatic Nuisance Species Task Force's definition of non-indigenous species is an aquatic species not present in the location of interest at the time of European colonization. Dr. Bruggemann added that this definition includes the historical range of the species since colonization as well. Dr. Kapuscinski commented that not all non-indigenous species will necessarily pose a threat when released.

Dr. Moyle raised the question of the definition of a "novel" trait. Dr. Kapuscinski referred to her proposed definition on page 8 of the Draft Standards and emphasized that a novel trait is determined by the endpoint, the final trait. Dr. Moyle pointed out that even if a gene is not activated, it could be of concern. Dr. Kapuscinski responded that a rational way of dealing with those uncertainties will be very important.

Dr. Kapuscinski raised several other points:

1) Effective sterilization of organisms is a way for researchers to safely research modified organisms, and criteria for effective sterilization are necessary.

2) She would like help from ecologists on how to assess ecological interactions and roles of modified organisms.

3) The question of scale is an important one. Is it appropriate to declare research with a certain number of organisms more risky than research with a smaller number of organisms? How should that number be picked? Or is that concept altogether flawed?

Characteristics of the Receiving Ecosystem

Dr. Kapuscinski said work will be needed to assess the alteration of ecosystem structure or function as a result of the presence of a modified organism. Furthermore, she said she was concerned about the arrangement of the questions. If the research is dealing with a significantly modified organism, under what circumstances would it be possible that the characteristics of the ecosystem would allow for research with only negligible concern?

Dr. Mann and Dr. Moyle suggested that "behavioral role" be explicitly included in the flowchart step on "significant ecological interaction/role."

Dr. Dunham raised the issue of the importance of the naturalness or artificiality of the receiving ecosystem in terms of determining risk. He noted that there is controversy about the justification for keeping an ecosystem exactly the way it is. Dr. Hallerman commented that questions #14 and #15 in the Draft Standards may provide a way to ask the researcher about the ecosystems' naturalness. Dr. Kapuscinski commented that while artificiality of the ecosystem is an important factor in gauging risk, there is societal consensus that some altered ecosystems should be restored (such as the Great Lakes).

Dr. Langston asked whether it were possible to use criteria to distinguish ecosystems based on their "susceptibility" to introductions of modified organisms. Dr. Moyle and Dr. Mann responded that there are differing opinions among ecologists on whether or not that kind of criteria would be meaningful.

Dr. Colt suggested that a specific question might be added about the location of the research, as that can greatly minimize the risk of research.

Dr. Colt suggested that the Working Group might consider using a numerical scale for ranking levels of risk. Ms. Cordle noted

that a similar method of assessing risk was proposed by ABRAC during development of Research Guidelines, but had received many negative comments. Dr. Colt agreed that a numerical system may raise concerns because of the possibility or appearance of being weighted unfairly. However, he is concerned that partial concerns will need to be addressed somehow.

Culture Methods/Physical Confinement/Inspection

Dr. Kapuscinski raised several points:

1) A definition of "effective" containment will be necessary. We know that 100% effective containment is impossible.

2) Researchers will need to have the option of not meeting research standards and conducting an environmental risk assessment instead.

3) Fisheries specialists will need to be involved in aquaculture system inspections. They should assess the possibilities of a breach of confinement. She raised the question of whether Institutional Biosafety Committees have adequate expertise to serve as inspectors.

Dr. Mann responded by emphasizing that the standards will have an important educational function.

Dr. Colt raised the topic of facility safety and noted that the management of the aquaculture facility rather than the physical facility itself should be a primary concern, as the most significant breaches of safety have occurred because of intentional releases by workers in the facility or others.

After some discussion by Ms. Cordle and Dr. Dunham about the importance of management practices in determining the safety of aquaculture facilities, the Working Group agreed that the new title "Confinement: Facilities and Management" should replace the title "Physical Confinement".

After a comment by Dr. Mann on the varying sets of regulations different states have, the group decided that the introduction to the standards should emphasize that researchers need to consult state and federal agencies to be sure they comply with all applicable regulations and need for permits.

Structure and Scope

Dr. Colt raised a question about the whole arrangement of questions, as he thought the questions were suited more for field trials, rather than laboratory systems or commercial application. Dr. Kapuscinski agreed that some branching in the flowchart of

questions of the Draft Standards may be necessary to accommodate the variety of types of research.

In addition, Dr. Kapuscinski wondered if different questions may be necessary for researchers working with marine finfish, mollusks, and crustaceans.

Dr. Mann pointed out that there is such tremendous variation in the types of organisms and research methods being used that this document needs to be focused somehow, and perhaps only on how to develop physical systems to minimize risk.

Dr. Kapuscinski agreed that the document needs to have a focused scope, but that the goal for this meeting is to develop a starting structure which can be expanded and improved to fit the various topics people think are necessary. She added that performance standards should guide research on ways to reduce the potential risk of research with a particular organism expressing a novel or modified hereditary trait.

Dr. Bruggemann commented that in many instances, certainty or confidence that one of the aspects of the research project suggests there is little risk in conducting the research, then questions about the other aspects of the project become less important. (The three aspects of the research are 1) the characteristics of the organism, 2) the characteristics of the receiving ecosystem and 3) the containment/confinement system).

Dr. Dunham asked if gamefish are included in the definition of aquaculture, and if they will therefore be subject to the standards. Some discussion of the title of the document resulted, with Dr. Kapuscinski suggesting changing phrasing in the title of the Draft Standards from "... aquaculture research..." to "...aquatic animal research..." to ensure that all research on aquatic animals be included.

In response to a question raised by Dr. Colt, Dr. Langston responded that it is unclear if the Non-Indigenous Aquatic Species Act will be applied retroactively to require environmental assessments on continuous stocking programs. Dr. Bruggemann agreed that this is a very difficult issue. Dr. Kapuscinski and Ms. Cordle emphasized that the task of this Working Group is to address research with organisms with novel traits, not impacts of stocking. However, the research conducted in preparation for stocking could be included in the purview of the draft standards.

Dr. Kincaid said he supports using the linear framework of the flowchart. Ms. Cordle stressed that the standards should be process neutral to avoid controversy in the "process versus product" debate; a product of molecular biotechnology should not be treated differently from products derived from other methods

of genetic modification. The standards need to be based on risk, independent of the method of modification. Dr. Hallerman noted that the choice of the phrase "modified organism" reflects this. Dr. Kapuscinski asked the group to evaluate her definition of "modified" in their review of the document.

Dr. Dunham expressed his concern about the far-reaching implications of these standards, because of the possibility that they will be used to guide regulations. He agrees that while there are extreme ramifications if no standards are in place for recombinant DNA research, he is greatly concerned that when the standards are applied to breeding programs they will seriously disrupt aquaculture and genetic research in the country.

Dr. Kapuscinski said that she shares Dr. Dunham's concerns, and stressed the importance of the definition of "novel trait." She explained that the definition might not include the case, for example, where average growth rate has changed but it is in the range of past average growth ranges. Selective breeding exploits the variation already there, and the conundrum is that biotechnology allows the creation of something truly novel. Deciding where to draw the boundary between novel and not novel will be very important.

Dr. Dunham noted that as the standards stand now, he thinks they will have significant impacts on studies on polyploidy and hybrids. Ms. Cordle commented that the "concept of familiarity" from the National Research Council to which she referred in her opening remarks may be useful.

After some discussion about the whole format, the group agreed that the linear structure was adequate. Dr. Kincaid suggested that the group evaluate the suitability of dividing the culture methods section of the Draft Standards to separate marine finfish from mollusks and crustaceans.

In response to questions from Dr. Kapuscinski, Dr. Mann explained that research on marine organisms, especially invertebrates, is not much past the observational stages. Dr. Dunham noted that there is some work taking place on modified oysters, for example. Dr. Mann noted that because marine organism must be released to be propagated, fitness in the natural environment is a goal of the manipulation. Therefore, concerns about marine species are significantly different from those regarding freshwater species.

Dr. Colt argued against separate performance standards for marine species, saying that whether or not organisms can be grown does not determine the risk of the organism.

There was some discussion about the potential for designing safety constructs into the traits of the organisms, though Dr. Bruggemann noted that, due to several limitations, this is

not as great an interest in the biotechnology field as it used to be.

Mesocosm Research

Dr. Colt raised the issue of mesocosm research. Dr. Kapuscinski suggested that the performance standards be designed to include mesocosm research. Dr. Dunham agreed that mesocosm research standards are crucial, because this research is the connection between experimental work and commercialization.

Dr. Mann pointed out that mesocosm research in marine systems is extremely difficult because of the large scale of organism numbers and their environments required to get meaningful results. He pointed out the usefulness of modeling in marine research and in risk assessment. Dr. Moyle commented that future strides in ecology will be in prediction of ecosystem changes.

Design of the Workshop

After a break for lunch, Dr. Kapuscinski gave an overview of the proposed workshop design, explaining that it is intended to include a broad diversity of experts, such as people with background in biological processes at the genome and cell level, organism level, population and ecosystem level, as well as people with other expertise, such as ecology of diseases and risk assessment. Aquaculture engineers and people working in government agencies will also be included.

As proposed, the 2 1/2 day event would begin with background talks in the morning of the first day. The bulk of the work would be done in small interdisciplinary groups. These small groups would reconvene to report to the whole workshop.

The purpose of small groups would be to provide a second layer of review/revision of the Draft Performance Standards. A rapporteur would be assigned and group discussions might be taped.

This experts meeting would be the last major input to the draft performance standards. The Draft Performance Standards would then be presented to ABRAC and given to USDA.

Dr. Moyle questioned whether a workshop is necessary, pointing out that a simple approval of the draft standards may not be very useful. Dr. Kapuscinski pointed out that it would be a good opportunity to educate a diverse group of people. Ms. Tibbets raised the point that the workshop would also be a good chance to hear from those who may differ in opinion from the Working Group members on the Draft Performance Standards. Dr. Dunham pointed out that acceptance by a broad group of experts would give the standards greater credibility.

Dr. Moyle suggested that an alternative to the workshop would be to send many people copies of the document and perhaps pay some people to do detailed reviews. Dr. Kapuscinski said that the workshop format will probably work well with specific objectives assigned to each invited participant and special preparation by the participants prior to the workshop, and said that she thought a positive outcome for the draft standards would be more likely if more people are involved in an interactive dialogue.

Dr. Hallerman suggested that the last day of the event be devoted to discussing the kinds of experiments necessary to address the uncertainties of environmental impacts, and future research needs and directions for aquatic biotechnology.

Ms. Cordle noted that the Working Group should not underestimate the length of time it may take to discuss the performance standards and reach general agreement. While Dr. Hallerman's suggestion could be a valuable addition to the meeting, the first priority must be assuring sufficient time to complete the standards.

Participation

Dr. Mann raised a question about the number of people to be invited, and noted that 100 people seemed too large a group. Dr. Kapuscinski responded that she anticipated inviting 40 participants, each of whom would receive a draft of the standards before the meeting and would be asked to prepare comments on particular sections. Because the meeting would be open to the public, the total number of persons attending might be as high as 100.

The group of 40 would be divided into four or five small groups, and the public attenders would be able to observe the working groups.

Dr. Colt suggested that people from the commercial biotechnology industry would add a different perspective and should be included. Dr. Kapuscinski said she is interested in sending them drafts for comments early in the development of the standards.

The following suggestions were made about other specialists who should be included in the workshop: molecular biologists, nutritionists, disease specialists, population dynamics specialists, invertebrate specialists and population geneticists.

Dr. Kapuscinski suggested the Ecological Society of America and the American Fisheries Society should be represented at the workshop.

Ms. Tibbets asked who would make the final decisions about who will be invited as participants. Dr. Kapuscinski said she will

send the master list of suggested participants to the Working Group members, who will help to decide who attends. Ms. Cordle asked that the Working Group strive for diversity, and asked that members give special thought to finding qualified experts among minority groups to participate.

Dr. Kapuscinski asked that nominations of participants be sent to her by November 2. A form to use for the nominations was distributed.

Date and Location

Dr. Kapuscinski said that the experts workshop was planned for early August 1993, so as not to conflict with or be too close to the American Fisheries Society meeting scheduled for August 30 to September 2, 1993. Tentative workshop dates were given as sometime in the week of Aug. 9th - 13th, and preferably close to a weekend. The closing session on the final half day could extend into the late afternoon. The workshop would be held in the Twin Cities, Minnesota, in part, because of the funding that is anticipated from Minnesota.

(Note: Accommodations were not available for the preferred week of August 9. Reservations have been made to hold the meeting at the Hubert Humphrey Center, August 18-20, 1993, and for hotel accommodations at the Holiday Inn Metrodome, Minneapolis, Minnesota.)

Publicity

Ms. Tibbets said that an excellent way to publicize the event would be make direct mailings to key individuals and to Journals and Societies.

Ms. Cordle suggested mailings also go to Regional Aquaculture Centers. Dr. Kapuscinski asked Dr. Bruggemann to send Ms. Cordle a list of environmental groups the Working Group could use as a resource for notification and selecting participants.
There was some discussion about the interest the local and national news media may have in the event. It was suggested that a press release might be prepared and that a spokesperson could be made available to the press to answer questions.

Assignments

Specific responsibilities were assigned for review and drafting of the standards as follows:

Characteristics of Modified Organisms

Point persons: Dr. Hallerman and Dr. Kincaid

Collaborators: Dr. Bruggemann, Ms. Cordle, (Dr. Bern - to be contacted by Dr. Kapuscinski)

Characteristics of Receiving Ecosystems

Point person: Dr. Kapuscinski
Collaborators: Dr. Moyle, Dr. Mann (with special focus on marine systems)

Culture Methods/Confinement: Facilities and Management

Point person: Dr. Colt
Collaborators: Dr. Dunham, Mr. William Wolters

Inspection

Point person: Ms. Cordle
Collaborators: Dr. Hallerman, Dr. Dunham

Dr. Mann agreed to review the structure of the whole document and provide suggestions for ways to adequately address mollusks and crustaceans.

Dr. Althaea Langston agreed to provide information for an introduction to address the connection between these performance standards and the proposed Research Protocol and approval procedure proposed for non-indigenous species, under the Aquatic Nuisance Species Program.

Dr. Kapuscinski asked that comments on the Draft Standards be sent to her by December 15th. A revision could then be distributed by mid-January. Dr. Kapuscinski asked that the Working Group pay particular attention to footnotes in the Draft Performance Standards, many of which may end up being moved into the text, and submit their thoughts on the questions posed in the handout.

Dr. Kapuscinski and Ms. Cordle agreed to draft a tentative agenda for the Workshop, and set a date and find a location in the Twin Cities for the Workshop. Reservations have been made to hold the meeting at the Hubert Humphrey Center, August 18-20, 1993, and for hotel accommodations at the Holiday Inn Metrodome, Minneapolis, Minnesota.

The group asked if it would be possible to reconvene the working group in March. Ms. Cordle said funding may not be available. She agreed to look into the possibility and make arrangements if funds are available. If a meeting isn't possible, a conference call to discuss the revision might be arranged.

Summary of Deadlines for Working Group Members:

NOVEMBER 2: Return lists of suggested workshop participants to Dr. Kapuscinski. FAX Number (612) 625-5299.

DECEMBER 15: Submit comments on Draft Performance Standards to Dr. Kapuscinski. If preferred, handwritten, rather than typed comments, may be sent.

Dr. Kapuscinski adjourned the meeting at 3:10 p.m.

Approved:

Alvin L. Young

ALVIN L. YOUNG
Executive Secretary

Anne R. Kapuscinski

ANNE R. KAPUSCINSKI
Chair

Performance Standards for Aquaculture Research Systems with Modified Organisms

NCN = no confinement necessary

START

↓

Characteristics of Modified Organism

- novel hereditary trait or trait regulation? —no→ NCN
- survive & reproduce in ecosystem? —no→ NCN
- effective sterilization applied? —no→ NCN
- significant ecological interaction/role? —no→ NCN
- "few" or "many" modified organisms? —few→ NCN

↓

Characteristics of Receiving Ecosystem

- interbreeding w/ conspecifics?
- hybridization?
- endangered, threatened, or sensitive species?
- ecosystem structure or function altered?

→ level of concern?

↓

Culture Methods

- checklist of practices that reduce chances of escape

↓

Physical Confinement

- is physical confinement effective? —no→ redesign & go to start

↓

conduct environmental risk assessment

Inspection

- provision for effective inspection? —no→ adopt inspection

↓

do environ. risk assessm.

system meets performance standards

↓

END

---------> DISCUSSION DRAFT, OCTOBER 15, 1992 <----------

PERFORMANCE STANDARDS FOR PROPOSED EXPERIMENTS INVOLVING AQUATIC MODIFIED ORGANISMS[1]

Note: Superscripts refer to footnotes which should help the researcher answer the questions posed.

I. Characteristics of Modified Organism and Receiving Ecosystem

This section establishes the level of concern associated with a modified organism, and may suggest biological containment measures.

Ia. *Characteristics of the Modified Organism.*

1. Does the organism express a novel hereditary trait?[2]
2. Does the organism express any hereditary trait under novel regulatory control?[3]

If "yes" to either question 1 or question 2, continue with question 3. If "no" to both questions 1 and 2, no confinement needed.

3. Can the modified organism survive in the receiving ecosystem?[4,5]
   - Neither within nor beyond 1 km from site of proposed experiment, no confinement needed.
   - Either within or beyond 1 km from site of proposed experiment, continue with question 4.

4. Can the modified organism reproduce in the receiving ecosystem?[4,6]
   - Neither within nor beyond 1 km from site of proposed experiment, no confinement needed.
   - Either within or beyond 1 km from site of proposed experiment, continue with question 5.

5. Is it feasible to sterilize this organism?
   - Yes. Continue with question 6.
   - No. Go to Section II.
   - Don't know. Go to Section II.

6. Taking into account the level of sterility achievable and the scale of the proposed experiment (in terms of total population size), how many individuals will be fertile (i.e., sterility not achieved) during the entire course of the project?[7]
   - Ten or fewer. No confinement needed.
   - More than ten. Go to Section II.

   If a, b, or c, ---> level of concern.

Ib. *Ecological Role of the Modified Organism.*

7. Does the modified organism interact "significantly" with other organisms in the receiving ecosystsm?[8]

8. Does the modified organism play a key role in ecosystem processes?[9]

9. Are answers to questions 7 and 8 based on data from direct tests for presence or absence of novel performance traits that could affect ecological interactions and roles of the modified organism?[10]

   If "yes" to questions 7 or 8, and "yes" to question 9, continue with question 10.

   If "no" to questions 7 and 8, and "yes" to question 9, no confinement needed.

   If "no" to question 9, go to Section II.[11]

10. What numbers of modified organisms are at issue?[12]
    If "few," no confinement needed.
    If "many," go to Section II.

    If a, b, or c, --->level of concern.

Ic. *Characteristics of the Receiving Ecosystem.*

11. Is there a population of conspecifics in the receiving ecosystem with which escaped modified organisms can interbreed?

12. Is there a population of a closely related species with which escaped modified organisms can hybridize?

13. Are there endangered, threatened, or sensitive species in the receiving ecosystem that would be negatively impacted by interaction with the modified organism?[13]

14. Would the structure of the receiving ecosystem be vulnerable to perturbations posed by the modified organism?[14]

15. Would the function of the receiving ecosystem be vulnerable to perturbations posed by the modified organism?[15]

If a,b,c, ---> level of concern

II. Culture Methods

Adoption of precautionary management practices reduces the likelihood of escape of modified organisms, but alone is not enough to achieve confinement.

16. At sexual maturity, will the sexes be held in separate units, except in situations when common rearing is needed to induce intentional reproduction?

17. For species requiring natural conditions for spawning, will the units used to hold spawners be treated in such a way as to eradicate or prevent escape of left-over zygotes or other early life stages after completion of spawning?

18. Will the experiment be conducted on the smallest scale necessary to provide statistically robust tests of performance?

19. Will the smallest, most difficult-to-confine life stages be cultured under containment conditions?[16]

20. At earliest feasible life stage, will all modified individuals be marked, branded, or otherwise identified?[17]

21. Will careful record-keeping be practiced for groups of organisms held in each rearing unit?[18]

22. At the end of the project, will organisms not needed for future research be destroyed in a fail-safe manner?

If yes to all of questions 16-20, continue with Section III.

If "no" to any of questions 16-20, consider alteration of experimental design.

III. Physical Confinement

This section helps the researcher to determine whether confinement adequate to meet the level of concern associated with the modified organisms has been achieved, and suggests physical measures for achieving confinement. How does level of concern fit as an input for this section?

Answer these questions for *every* incubation and rearing unit involved in the proposed project.

23. Is the proposed site located above the 100-year flood plain of any waterbody, or in marine systems, above the area of the 100-year storm surge?

24. Is there an adequate security system, comprising the facility itself and monitoring practices, to ensure against human encroachment?[19]

25. Have adequate measures been taken to prevent animal encroachment?[20]

26. Have measures, including back-up systems and culture practices, been taken to prevent escape of organisms via influent water?[21]

27. Have measures, including back-up systems and culture practices, been taken to prevent escape of organisms via effluent water?[22]

28. In the case of natural disasters (acts of god), would the physical system prove fail-safe for escape of organisms?[23]

29. Are there operational procedures in place to maintain functioning of all physical confinement measures?[24]

30. In event of unforseen clogging of rearing unit drains or flooding (outdoor units), is there sufficient freeboard to prevent overflow or alarm system to warn of impending overflow?

If "yes" to all of questions 23 through 30, go to Section IV.

If "no" to any of questions 23 through 30, redesign project and go back through flowchart.

IV. Inspection

This section ensures proper execution of the confinement protocol by providing for local inspection of facilities and practice.

IVa. *Prior to Start of Project*

31. Have competent fisheries experts[25] representing the responsible federal agency inspected the proposed project site for efficacy of confinement (for exclusions from NEPA), based on characteristics of the modified organism, culture methods, and physical culture system laid out in Sections I-III above?

IVb. *For Duration of Project*

32. Have provisions been made for unannounced inspections (decide number based on confinement level) of efficacy of confinement, based on characteristics of the modified organism, culture methods, and physical culture system laid out in Sections I-III above?[26]

If "yes" to questions 31 and 32, effective confinement has been achieved, and no NEPA-based oversight is needed.

If "no" to either questions 31 or 32, consider addition of inspections and re-evaluate questions posed in Section IV, or submit Environmental Assessment under NEPA.

Footnotes

1 These performance standards are based on guidelines proposed by the Working Group for Aquaculture Biotechnology and Environmental Safety, of the Agricultural Biotechnology Research Advisory Committee, U.S. Department of Agriculture.

2 A novel trait might be (1) expression of a compound not normally found in the species, e.g., antifreeze polypeptide in Atlantic salmon or the coat protein of the IHN (infectious hematopoeitic necrosis) virus in Pacific salmon, or (2) a change in a quantitative trait

(Kapuscinski and Hallerman 1991), including changes in: a metabolic rate, tolerance of a physical environmental factor, a behavior, resource or substrate use, or resistance to disease, parasite, or predation.

3 For example, mice expressing foreign genes for growth hormone with endogenous promoters were subject to the normal regulatory mechanisms that affect growth and did not exhibit enhanced growth (Wagner et al. 1983, Hammer et al. 1984). Other, non-endogenous regulatory sequences were necessary to drive expression of the growth hormone gene in order to yield enhanced growth (Pinkert et al. 1991). Hence, not only the structural gene, but also the regulatory elements of the introduced genetic construct are at issue in determining whether an organism is a modified organism.

4 Information on life history and environmental requirements of the host organisms is useful, but not sufficient to assess the life history and environmental requirements of the modified organism.

5 Based on knowledge of the life history, physical/chemical tolerances, and environmental requirements of the modified organism in relation to attributes of the receiving ecosystem, could it survive (a) in the immediate area of the receiving ecosystem, i.e., within 1 km, or (b) through dispersal through an area greater than 1 km, could it reach suitable habitat?

6 Based on knowledge of the life history, physical/chemical tolerances, and environmental requirements of the modified organism in relation to attributes of the receiving ecosystem, could it reproduce (a) in the immediate area of the receiving ecosystem, i.e., within 1 km, or (b) through dispersal through an area greater than 1 km, could it reach suitable habitat?

7 The likelihood of reproduction of modified organisms is a function of the number of fertile individuals, i.e., the scale and timing of escapes. The scale and frequency of introductions of fertile modified organisms into a particular environment will greatly influence the degree of ecological risk involved in execution of a proposed experiment (Kapuscinski and Hallerman 1991).

8 Consider predator-prey interactions, parasitism, mutualism, competition, and pathogenicity (Kapuscinski and Hallerman 1991, Tiedje et al. 1989).

9 Consider, for example, impacts on nutrient cycling and energy flow, and the keystone species concept

(Kapuscinski and Hallerman 1991, Tiedje et al. 1989).

10 Quantitiative traits

11 Performance evaluations of modified organisms are sorely needed to gain insight into their potential ecological impacts. Two complementary approaches are needed (Kapuscinski and Hallerman 1991): a battery of laboratory experiments, where a few environmental factors are varied while others are held constant; and studies in more ecologically realistic but securely confined mesocosms (Odum 1984, Voshell 1989).

12 Numbers at issue. Need help.

13 Consult your state fisheries and wildlife agency and the U.S. Fish and Wildlife Service.

14 structure

15 function

16 I.e., static or recirculating aquaculture systems. Expert help needed in structuring this footnote.

17 To facilitate monitoring and retrieval of modified organisms in event of escape.

18 Record keeping.

19 Suitable measures against vandalism, theft, and entry of unauthorized individuals might include perimeter fencing, alarms, strict key control, and sign in/sign out procedures.

20 Measures might include skirting of perimeter fences and lining of ponds to prevent entry of burrowing animals, and bird netting.

21 Examples include vertical drop between outfall of influent pipes and culture vessels, screening the outfall of the influent pipes, in-line screening in influent pipes.

22 Examples include tank covers, standpipe screens, French drains, gravel traps, and empty ponds alongside ponds containing modified organisms. Discharge from facility into sanitary sewers does not alone provide effective confinement, as sewage treatment facilities are frequently bypassed during high-runoff events.

23 Consider power failures, floods, severe storms, and earthquakes.

24 Include personnel training and oversight, sufficiently frequent monitoring, and keeping records of all persons entering or leaving the site.

25 To qualify as an expert, an individual must be demonstrably familiar with the life history and ecological requirements of the host organism and the ecological attributes of the receiving ecosystem. More than one individual may be required to assemble the required expertise. The individual(s) should not be from the same institution as the principal investigator.

Literature Cited

Hammer et al. 1984

Kapuscinski, A.R., and E.M. Hallerman. 1991. Implications of introductions of transgenic fish into natural ecosystems. Canadian Journal of Fisheries and Aquatic Sciences 48(Suppl. 1):99-107.

Odum, E.P. 1984. The mesocosm. BioScience 34:558-562.

Pinkert, C.A., D.L. Kooyman, and T.J. Dyer. 1991. *in* N. First and F.P. Haseltine, eds. Transgenic animals. Butterworth-Heenemann, Boston.

Tiedje, J.M., R.K. Colwell, Y.L. Grossman, R.E. Hodson, R.E. Lenski, R.N. Mack, and P.J. Regal. 1989. The planned introduction of genetically engineered organisms: Ecological considerations and recommendations. Ecology 70:298-315.

Voshell, J.R., Jr., ed. 1989. Using mesocosms to assess the aquatic ecological risk of pesticides: Theory and practice. Entomological Society of America, Miscellaneous Publications 75:1-88.

Wagner

Cite Fonsi description of Rex's facility.

Revision of Discussion Draft Performance Standards (10/15/92)

Help is needed at least on items identified below. All items are open to discussion.

[numbers refer to question (q) or footnote (f) numbers in draft]

I. Characteristics of Modified Organism and Receiving Ecosystem
q1, q2 - definition of modified organism

q3, q4 - criteria for geographic range of concern for survival, reproduction

q6 - criteria for effective sterilization

q10 (f12) - criteria for scale of experiment viz a viz need for confinement

q11 to q15 - how use responses to questions about characteristics of receiving ecosystem to assign level of concern/risk

q14, q15 - need help on questions about ecosystem structure and function

II. Culture Methods
q18 - criteria for identifying smallest scale necessary for experiment

q19 (f16) - appropriate criteria for "containment"

q16 to q20 - more detail on handling a "no" response to any question

any additions, modifications to this section?

III. Physical Confinement
q23 to q30 - more detail on handling a "no" response to any question

any additions, modifications to this section?

IV. Inspection
any additions, modifications to this section?